

Appl. No. 10/767,329
Amdt. dated August 14, 2006
Reply to Office action of May 17, 2006

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REMARKS

Rejection of the claims under 35 USC §112:

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for lack of literal support for the term polypeptide-detergent complex. Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended claims 1 and 21 to recite a "polypeptide-surfactant complex", which has literal support in the specification. Support for "wherein the surfactant consists of a detergent" is supported in the specification on page 13 line 28, which states that a surfactant can be a detergent or a lipid, on page 14 lines 3-5, which defines a detergent, and the examples which utilize numerous surfactants readily recognized by those knowledgeable in the art as detergents.

Rejection of the claims under 35 USC §112:

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide enablement for the generic class of "dried polypeptide-detergent" complexes as claimed. Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended claims 1 and 21 to cite a detergent having a net charge opposite that of the charged polypeptide. Support for the amendment can be found in the specification on page 3 lines 7-14, page 7 line 5 to page 8 line 16.

Rejection of the claims under 35 USC §102

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by EP 0335133 as evidenced by US 5,939,536. Applicants respectfully disagree.

Lysophosphatidylcholine, which contains a single fatty acid alkyl chain, is a detergent formed by hydrolysis of phosphatidylcholine by the enzyme phospholipase A₂. Phosphatidylcholine, which contains two fatty acid alkyl chains, is a lipid. 5,939,536 teaches that a lysophosphatidylcholine is a detergent and does not teach that a phosphatidylcholine, as used by EP 0335133, is a detergent.

Claims 1-8 and 21-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by US 5,858,398 as evidenced by US 3,578,591. Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended claims 1 and 21 to recite a composition

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or process "consisting essentially of..." US 5,858,398 teaches a composition consisting of: a pharmaceutical agent, at least on water soluble phospholipid, at least on lipid soluble phospholipid, at least one non-ionic detergent having an HLB value of 15 or less, at least one non-ionic detergent having an HLB value of 6 or less, and at least one water soluble sterol.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-8 and 21-24 should be allowable.

Respectfully submitted,



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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: March 1, 2006


Kirk Ekena